The bases for these rejections are virtually identical to those previously articulated in the Office Action of December 18, 2001.

In construing the Chen et al. disclosure, the Examiner has inappropriately applied the doctrine of inherency by stating that the claimed physical properties, in this case elongate particles and void volume, are present in the prior art material "to some extent" even though they are not explicitly recited.

As previously noted by applicants, there is no disclosure anywhere in Chen et al. of *elongate bone derived elements*. The only bone-derived elements disclosed in Chen et al. are demineralized bone particles or demineralized bone powder. Nothing is said in Chen et al. regarding the shape of the demineralized bone "particles". The shape of the demineralized bone "powder" in Chen et al. is anything but elongate. According to the Examiner, "The collagen fleece . . . can be interpreted to contain fiber-like particles according to the definition of a fleece (a fabric or membrane of fibrous material). Also, it should be noted that since not all the particles are going to be 'perfect' spheres, it is evident that there will be elongate particles present in the sheet." However, there is no express disclosure of elongate particles and, in fact, the Chen et al. examples illustrate a product produced from collagen and demineralized bone particles (Examples 1 and 2), where a thick slurry of the combined materials is *blended in a Waring Blender*. Thus, even if elongate demineralized bone particles were originally present in the slurry (and, of course, Chen et al. is completely silent on this point), they would have been broken up or

chopped into non-elongate particles before the final product, a sponge, could be formed.

The doctrine of inherency holds that a property is necessarily present, given the nature of the disclosure, and is therefore disclosed even though the reference makes no express mention of the property. "If the prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is 'inherent' in its disclosure. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999) (quoting *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). Inherency is not, however, "established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Continental Can,* 948 F.2d at 1269, 20 U.S.P.Q.2d at 1749 (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). As is clear from the above cases, there is no such thing as inherency "to some extent". Either the "not greater than about 32 percent" void volume limitation of the claims is inherently disclosed in Chen et al. or it is not disclosed at all.

In re Oelrich is especially relevant to the instant case. In *In re Oelrich*, the claim at issue recited an apparatus specially adapted for moving steering fins on guided missiles and had been held by the Board to be anticipated by U.S. Patent No. 3,430,536 to Oelrich. "The device which is the

subject of the Oelrich patent 'was employed only with the then available steering fins which they characterize as 'high inertia' loads. . . . The frequency at which this "'high inertia' load system is operated is stated to be *above* the critical (resonant) frequency of the system." 666 F.2d at 579, 212 U.S.P.Q. at 324 (emphasis in original) (citations omitted). The allowed method claims and apparatus claim directed the use of a carrier frequency *below* the critical frequency of the system. While the PTO had argued that the Oelrich patent inherently performed the function of the disputed claim in that the carrier frequency which could be used in a low inertia system *may* fall within the range of carrier frequencies in a high inertia system, the Court rejected this argument noting that "the mere fact that a certain thing may result from a given set of circumstances is not sufficient." 666 F.2d at 581, 212 U.S.P.Q. at 326.

Here, as in *In re Oelrich*, there is nothing in Chen requiring that the void volume is necessarily not greater than about 32 percent. Chen et al. does not relate the void volume of the disclosed implant, a sponge, with a particular quality of the implant. In the claims of the subject application, the recitation of less than 32% pore volume relates directly to the improved properties of this osteoimplant. Thus, in table 5 of the application, an implant prepared in accordance with the prior art (and containing a void volume considerably in excess of applicants' claimed maximum) had a much increased tendency to at least partially return to its original bent configuration than an implant prepared in accordance with the claimed invention. Applicants' implant for the most part exhibited no such tendency, or "memory". The advantage of a flexible membrane which exhibits little if any memory is that it will tend to remain

conformed to the shape of the site where it is implanted, a desirable characteristic for many kinds of orthopedic surgical procedures. Accordingly, while Chen *may* provide a void volume not greater than 32%, it is not necessarily present and thus it cannot be inherent in Chen.

In addition, the Examiner argues that "the claims do not require that the composition have a void volume because applicant's range includes **0%**" (see Office Action at p. 4) (emphasis in original). This argument clearly requires a tortured reading of applicant's Claim 1, which for ease of reference, is set forth below

> 1. An osteogenic implant in the form of a flexible sheet comprising a coherent mass of bone-derived particles, the coherent mass formed at least in part from elongate bone-derived elements optionally in combination with bone powder, the osteoimplant possessing an average void volume of not greater than about 32%.

Clearly, Claim 1 requires a void volume as it is expressly directed to an osteoimplant "*possessing* an average void volume of not greater than about 32%" (emphasis added). Contrary to the Examiner's assertion, a range is not provided which would include an osteoimplant lacking a void volume when the language of Claim 1 clearly provides that its osteoimplant possesses a void volume. Moreover, the specification consistently notes the presence of a void volume: *see, e.g.*, specification page 4, line 13 (". . .having a void volume. . ."); p. 6, lines 1-4 (". . .relatively small void volume of the osteoimplant of this invention. . ."); p. 9, lines 3-7 (defining void volume to include liquids); and table 1 of the application, which compares an implant prepared in accordance with the

prior art (and containing a void volume considerably in excess of applicants' claimed maximum) and an implant prepared in accordance with the claimed invention (clearly possessing a void volume).

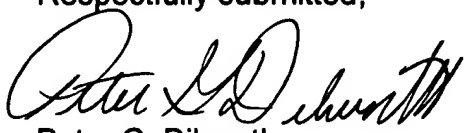
Applicants therefore respectfully submit that Chen et al. fails to anticipate any of Claims 1, 3-7, 10-13 and 33-35.

Finally, the Examiner has maintained the rejection of Claims 2, 8 and 9 under 35 U.S.C. §103(a) for obviousness over Chen et al. The Examiner concedes that Chen et al. does *not* disclose a thickness of 50-2000 microns which is mechanically shaped in a coherent mass of elongate bone particles to a specific 3-D architecture, but that such a thickness and shaping would be obvious to one of ordinary skill in the art as it is utilized in various procedures. Applicants' refer the Examiner to the experimental data presented in Table 5 of the specification where the almost total lack of memory of the claimed implant contrasts with the tendency of the prior art implant to return to its original shape. Chen et al. fails to suggest the structural parameters that make this property possible, i.e., applicants' use of elongate bone particles and providing less than about 32% average void volume.

In view of the foregoing, Claims 2, 8 and 9 are believed to define patentable invention over Chen et al.

Reconsideration and allowance of Claims 1-13 and 33-35 by the Examiner are once again respectfully requested.

Respectfully submitted,



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